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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,512	03/14/2002	Jacques Galipeau	2626-I-001	4833
23565	7590	05/19/2004	EXAMINER	
KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			HILL, MYRON G	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,512

Applicant(s)

GALIPEAU, JACQUES

Examiner

Myron G. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1- 17 is/are pending in the application.
- 4a) Of the above claim(s) 1- 12 and 14- 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/30/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group V in paper filed 2/25/04 is acknowledged. The traversal is on the ground(s) that Groups II- IX be regrouped as one for the following reasons: that there is Unity of Invention and the ISA searched all the groups, that multiple products are not excluded from one application, and that the examiner failed to show that a special feature was not found in Groups II- IX. This is not found persuasive. The application was assessed for Lack of Unity as appropriate for a 371. The Lack of Unity is based on a showing of a special technical feature for claim 1. The examiner provided art to show lack of special technical feature of claim 1 as defined by PCT Rule 13. Applicant did not argue or dispute the art cited for the special technical feature of claim 1 that was used to show Lack of Unity. The examiner is not required to provide a Lack of Unity for each claim or group.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1- 12 and 14- 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

This action is on claim 13.

Information Disclosure Statement

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A signed and initialed copy of the IDS filed January 30, 2002 is enclosed.qw

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what the metes and bounds of “therapeutic [first nucleotide sequence]” is. It is not clear what the metes and bounds of “co-dominantly” is. It is not clear what is meant by “nucleobase” in the last line and is treated in this action as meaning nucleoside analog. It is not clear what the outcome of “treat” is. It is not clear what is meant by sequence encoding a “marker” and this term is taken to include a selectable marker as in neo gene which can be selected for by G-418 antibiotic in the culture medium.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method using thymidine kinase (TK) and gancyclovir (GCV) as a combination that is therapeutic, does not reasonably provide

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enablement for all therapeutic nucleotide sequence and nucleobase analogs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include: (1) the nature of the invention, (2) the state of the prior art, (3) the presence or absence of working examples, (4) the amount or direction or guidance presented, (5) the quantity of experimentation necessary, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The specification does not set forth sufficient teachings to allow one skilled in the art to use the claimed method of using therapeutic nucleotide sequences and nucleobase analogs to treat a tumor. (1) the nature of the invention is to administer to a mammalian subject suspected of having a tumor an expression vector comprising a therapeutic gene and a nucleobase analog. (2) the state of the prior art, the prior art lacks predictability in regards to this method of treatment as shown by lack of success in all patients, see Deliganis *et al.* table top left of page 1404). Using viral vectors to treat tumors is an experimental and not a conventional therapy.

The specification does not provide other combinations of therapeutic nucleotide sequences and nucleobase analogs to treat a tumors. (4) the amount or direction or guidance presented, the specification provides evidence of using the specific

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combination of TK and GCV. The specification does not provide sufficient guidance to allow one skilled in the art to use the claimed method to treat tumors in all tissues of the body. The specification does not provide teachings to establish effective dosages or methods of administration to be effective in other tissues than brain. The specification does not provide any teaching as to how to administer the combination to effectively treat an animal or human. No working examples are provided which would provide sufficient guidance to allow one skilled in the art to practice the above embodiments of the invention with a reasonable expectation of success.

(5) the quantity of experimentation necessary, is high as it is not predictable that the therapeutic nucleic acid and nucleotide analog can be delivered to all possible tumor sites in effective doses. (6) the relative skill of those in the art is high. (7) the predictability or unpredictability of the art, the predictability based on the prior art is such that all types of tumors are not able to be treated. (8) the breadth of the claims, the specification provides insufficient guidance with regard to the scope of the claim. Therefore the instant invention is not enabled for the broadly claimed method of treating tumors.

Thus, the specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict the efficacy of the claimed method of treatment with a reasonable expectation of success. Moreover, the nature of the invention and the state of prior art have not provided any reasonable expectation of success in the treatment of the lung cancer.

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For the above reasons, it appears that undue experimentation would be required to practice the claimed inventions with a reasonable expectation of success.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The burden of the written description requirement in this application for therapeutic nucleic acid sequences and nucleobase analogs has not been met.

The written description in this case only sets forth thymidine kinase (TK) and gancyclovir (GCV) as a combination that is therapeutic.

Vas-Cath Inc. v. Mahurkar ((CAFC, 1991) 19 USPQ2d 1111), clearly states that "Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See Vas-Cath at page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). It is respectfully submitted that the instant specification only provides for the combination of TK and GCV and not all therapeutic nucleic acid sequences and nucleobase analogs as now claimed. It would not be expected that non thymidine nucleosides would function the same way with TK because they would not be phosphorylated. Also, the art predominately recognizes the combination of TK and GCV as a useful combination, see

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Deliganis *et al.* below. Accordingly, there is evidence that the full scope of the claimed invention was not in Applicant's possession as of the filing date sought.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see Vas-Cath at page 1115).

With the exception of TK and GCV, the skilled artisan cannot envision the method and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention and a reference to the components in terms of a genus. See *Fiers v. Revel*, ((CAFC, 1993) 25 USPQ 2d 1601) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*,((CAFC, 1991) 18 USPQ2d 1016).

Therefore only a method using TK and GCV, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Deliganis *et al.*

The claim is drawn to a method of treating a tumor comprising administering a retroviral expression vector and a nucleobase analog.

Deliganis *et al.* teach a method to treat tumors comprising administering a retroviral viral vector with a first nucleic acid sequence being therapeutic (TK) and administering GCV (Figures 1 and 2).

Deliganis *et al.* is silent on a nucleic acid sequence encoding a marker and co-dominantly expressed. Deliganis *et al.* administers cells that contain the vector. The claim is drawn to comprising and only requires administering a retroviral expression vector comprising nucleic acid sequences not particles of retroviruses.

It is a well known part of vector design to use a selectable marker when growing vectors in cell culture. Also, it is unclear also what is meant by co-dominantly but since the vector must express the selectable marker and must express TK, it must express both. The claim does not require a regulatable promoter so both nucleic acid sequences must be expressed in it as well.

Thus, Deliganis *et al.* anticipate the invention.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 13 is rejected under 35 U.S.C. 102(a) as being anticipated by Nalbantoglu *et al.* (Neurology 1999, from IDS).

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The claim is drawn to a method of treating a tumor comprising administering a retroviral expression vector and a nucleobase analog.

Nalbantoglu *et al.* disclose a method of treating tumors in a mammal comprising administering a therapeutic nucleic acid sequence (TK) and a nucleobase (GCV).

Thus, Nalbantoglu *et al.* anticipate the claimed invention.

Conclusion

No claim is allowed.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Myron G. Hill
Patent Examiner
May 16, 2004



JAMES HOUSEL
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5/17/04